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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,946	08/22/2001	Charles Chauveau	C1190/20008	5350

7590 04/16/2004

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT PAPER NUMBER

1616

DATE MAILED: 04/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b>	<b>Application No.</b> 09/830,946	<b>Applicant(s)</b> CHAUVEAU ET AL.	
	<b>Examiner</b> Sharmila S. Gollamudi	<b>Art Unit</b> 1616	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 18 March 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 18 March 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: \_\_\_\_\_.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_.

Applicant argues that there is no motivation to combine Liu et al and Ku et al and utilize the instant permeabilizing agent. Applicant argues that Liu et al solve the problem of "sticking" by utilizing magnesium stearate and thus there is not motivation to look outside of Liu et al.

Applicant's arguments have been fully considered but they are not persuasive. IT is acknowledged that Liu teaches that lubricants help in manufacturing of the tablet and help prevent the ejection sticking of the compressed formulation to the pressing dies and sticking. However, Ku teaches the combination of silicon dioxide and magnesium stearate has an excellent lubricating effect while minimizing any decline in tablet dissolution. Therefore, it is clear that Ku teaches an improved combination of magnesium stearate and silicon dioxide for overcoming the sticking problem without giving up dissolution of the tablet. Thus, there is clearly a motivation to look to Ku et al to yield an improved dosage form that is manufactured easily without jeopardizing the dissolution rate of the tablet.

Applicant's arguments pertaining to Augello et al are confusing. Applicant argues that Augello et al teaches the use of croscarmellose as a coating agent and as a disintegrant; therefore there is not motivation to utilize silica. It is further argued that the instant invention does not utilize croscarmellose as a coating agent.

Applicant's arguments have been fully considered but they are not persuasive. Firstly, the examiner points out that it is quite conventional in the art to utilize combination of disintegrants for the purpose of an additive effect for faster dissolution. Secondly, it is pointed out that the Augello et al teach the use of conventional additives

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in the composition such as flow aids. Meyers et al not only teaches the use of silica as a flow aid to reduce particles friction but also as a disintegrant. Therefore, a skilled artisan would not only be motivated to use silica to provide for easier manufacturing of the dosage form but also for its additive effect as a disintegrant to provide for a rapid dissolving dosage form. It is the examiner's position that the use of conventional additives such as silica or silicon dioxide is within the skill of a pharmaceutical artisan. Lastly, it is pointed out that the claims are directed to a product claim and the use of a certain component does not hold patentable unless denotes a structural limitation. Therefore, since the claims only require the presence of croscarmellose and clearly Augello et al teach croscarmellose, the claims are not distinguishable over the prior art.

Therefore, the rejection of all the claims is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-242-0614. The examiner can normally be reached on M-F (8:00-5:00) with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SSG

  
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